

IN THE UNITED STATES DISTRICT COURT  
FOR DISTRICT OF DELAWARE

ICU MEDICAL, INC.,

Plaintiff / Counter-Defendant,

v.

RYMED TECHNOLOGIES, INC.,

Defendant / Counter-Plaintiff.

Civil Action No. 07-468-JJF

**JURY TRIAL DEMANDED**

**DEFENDANT RYMED TECHNOLOGIES, INC.’S ANSWER TO  
ICU MEDICAL, INC.’S COMPLAINT FOR PATENT INFRINGEMENT,  
DEFENSES, AND COUNTER-PLAINTIFF RYMED’S COUNTERCLAIMS**

Defendant RyMed Technologies, Inc. (“RyMed) hereby responds to the numbered Paragraphs of the Complaint filed by Plaintiff ICU Medical, Inc. (“ICU”) as follows:

**PARTIES**

1. RyMed lacks knowledge and information sufficient to admit or deny the allegations contained in Paragraph 1 of the Complaint, and therefore denies the allegations contained in Paragraph 1 of the Complaint.

2. RyMed admits that it is a corporation duly organized and existing under the laws of the State of Delaware, and having a principal place of business at 137 Third Avenue North, Franklin, Tennessee. RyMed denies the remaining allegations contained in Paragraph 2 of the Complaint.

**JURISDICTION AND VENUE**

3. RyMed admits the allegations contained in Paragraph 3 of the Complaint.

4. RyMed admits that this Court has jurisdiction over RyMed because RyMed is a Delaware corporation. RyMed denies the remaining allegations contained in Paragraph 4 of the Complaint.

5. RyMed admits the allegations contained in Paragraph 5 of the Complaint.

6. RyMed admits the allegations contained in Paragraph 6 of the Complaint.

### **THE PATENTS IN SUIT**

7. RyMed denies the allegations contained in Paragraph 7 of the Complaint.

8. RyMed admits that the title of U.S. Patent No. 5,873,862 (“the ‘862 patent”) is “Medical valve and method of use” and that the ‘862 patent appears on its face to have issued on February 23, 1999. RyMed admits that a copy of the ‘862 patent is attached to the Complaint as Exhibit B. RyMed lacks knowledge and information sufficient to admit or deny the remaining allegations contained in Paragraph 8 of the Complaint, and therefore denies the remaining allegations contained in Paragraph 8 of the Complaint.

9. RyMed admits that the title of U.S. Patent No. 5,928,204 (“the ‘204 patent”) is “Medical valve and method of use” and that the ‘204 patent appears on its face to have issued on July 27, 1999. RyMed admits that a copy of the ‘204 patent is attached to the Complaint as Exhibit C. RyMed lacks knowledge and information sufficient to admit or deny the remaining allegations contained in Paragraph 9 of the Complaint, and therefore denies the remaining allegations contained in Paragraph 9 of the Complaint.

10. RyMed admits that the title of U.S. Patent No. 6,572,592 (“the ‘592 patent”) is “Medical valve and method of use” and that the ‘592 patent appears on its face to have issued on June 3, 2003. RyMed admits that a copy of the ‘592 patent is attached to the Complaint as Exhibit D. RyMed lacks knowledge and information sufficient to

admit or deny the remaining allegations contained in Paragraph 10 of the Complaint, and therefore denies the remaining allegations contained in Paragraph 10 of the Complaint.

**COUNT I**

**DIRECT INFRINGEMENT OF THE ‘866 PATENT**

11. RyMed’s answers to the allegations contained in Paragraph 11 of the Complaint are set forth in Paragraphs 1-10 above and are incorporated by reference as if set forth in full here.

12. RyMed denies the allegations contained in Paragraph 12 of the Complaint.
13. RyMed denies the allegations contained in Paragraph 13 of the Complaint.
14. RyMed denies the allegations contained in Paragraph 14 of the Complaint.

**COUNT II**

**DIRECT, INDUCED, AND/OR CONTRIBUTORY INFRINGEMENT  
OF THE ‘862 PATENT**

15. RyMed’s answers to the allegations contained in Paragraph 15 of the Complaint are set forth in Paragraphs 1-14 above and are incorporated by reference as if set forth in full here.

16. RyMed denies the allegations contained in Paragraph 16 of the Complaint.
17. RyMed denies the allegations contained in Paragraph 17 of the Complaint.
18. RyMed denies the allegations contained in Paragraph 18 of the Complaint.

**COUNT III**

**DIRECT INFRINGEMENT OF THE ‘204 PATENT**

19. RyMed’s answers to the allegations contained in Paragraph 19 of the Complaint are set forth in Paragraphs 1-18 above and are incorporated by reference as if set forth in full here.

20. RyMed denies the allegations contained in Paragraph 20 of the Complaint.

21. RyMed denies the allegations contained in Paragraph 21 of the Complaint.
22. RyMed denies the allegations contained in Paragraph 22 of the Complaint.

**COUNT IV**

**DIRECT, INDUCED, AND/OR CONTRIBUTORY DIRECT INFRINGEMENT  
OF THE ‘592 PATENT**

23. RyMed’s answers to the allegations contained in Paragraph 23 of the Complaint are set forth in Paragraphs 1-22 above and are incorporated by reference as if set forth in full here.

24. RyMed denies the allegations contained in Paragraph 24 of the Complaint.
25. RyMed denies the allegations contained in Paragraph 25 of the Complaint.
26. RyMed denies the allegations contained in Paragraph 26 of the Complaint.

**REPLY TO ICU’S PRAYER FOR RELIEF**

RyMed denies that ICU is entitled to any relief, either as requested in ICU’s Complaint or otherwise.

**AFFIRMATIVE DEFENSES**

For its further and separate defenses to the allegations of the Complaint, RyMed avers as follows:

**FIRST AFFIRMATIVE DEFENSE**

RyMed has not and does not willfully or otherwise infringe, contribute to infringement of, or actively induce others to infringe, either literally or by application of the doctrine of equivalents, any valid and enforceable claim of the ‘866, ‘862, ‘204, or ‘592 patents, nor has it ever done so.

**SECOND AFFIRMATIVE DEFENSE**

All of the claims of the ‘862, ‘204, or ‘592 patents are invalid and/or unenforceable for failure to meet one or more of the conditions of patentability specified

in Title 35 of the United States Code, including, but not limited to, 35 U.S.C. §§ 102, 103, 112, and/or 115.

**THIRD AFFIRMATIVE DEFENSE**

ICU is estopped from construing the claims of the ‘862, ‘204, or ‘592 patents in such a way as may cover RyMed’s activities by reason of, among other things, statements made in the ‘862, ‘204, or ‘592 patents, amendments and/or statements made in or to the United States Patent and Trademark Office during the prosecution of the applications that issued as the patents-in-suit, prior statements made in this or any other Court, prior rulings of this or any other Court, and/or ICU’s prior conduct.

**FOURTH AFFIRMATIVE DEFENSE**

ICU’s claims for relief are barred by the doctrine of estoppel.

**FIFTH AFFIRMATIVE DEFENSE**

ICU’s claims for relief are barred by the doctrine of laches.

**SIXTH AFFIRMATIVE DEFENSE**

ICU’s claims for relief are barred by the doctrine of prosecution laches.

**SEVENTH AFFIRMATIVE DEFENSE**

ICU’s claims for damages and injunction are barred, in whole or in part, by operation of the applicable statutes, including 35 U.S.C. §§ 286 and 287.

**EIGHTH AFFIRMATIVE DEFENSE**

RyMed reserves the right to assert any other defenses that discovery may reveal, in the event discovery or other analyses indicate that additional affirmative defenses are appropriate.

**COUNTERCLAIMS**

Defendant and Counter-Plaintiff RyMed hereby pleads the following counterclaims against Plaintiff and Counter-Defendant ICU:

**PARTIES**

1. Defendant and Counter-Plaintiff RyMed is a corporation organized and existing under the laws of the State of Delaware and has a principal place of business at 137 Third Avenue North, Franklin, Tennessee.

2. Upon information and belief, Plaintiff and Counter-Defendant ICU is a corporation duly organized and existing under the laws of the State of Delaware, with its principal place of business is 951 Calle Amanecer, San Clemente, California.

**JURISDICTION AND VENUE**

3. Jurisdiction of these counterclaims is based on 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

4. Venue is proper in this district pursuant to 28 U.S.C. § 1391.

**FIRST COUNTERCLAIM**

**DECLARATORY JUDGMENT OF NON-INFRINGEMENT AND INVALIDITY  
OF THE '866 PATENT**

5. RyMed realleges and incorporates herein by reference the matters alleged in Paragraphs 1-4 of these Counterclaims.

6. As demonstrated by ICU's commencement of this action, an actual and justiciable controversy exists between RyMed and ICU as to the non-infringement and invalidity of U.S. Patent No. 5,685,866 (hereinafter the '866 patent).

7. RyMed has not infringed and is not infringing any valid and enforceable claim of the '866 patent, either directly, indirectly, literally, or under the doctrine of equivalents.

8. The claims of the '866 patent are invalid and unenforceable for failure to meet one or more of the requirements of patentability specified in Title 35 of the United States Code, including, without limitation, 35 U.S.C. §§ 102, 103 and/or 112.

9. RyMed has no adequate remedy at law. The actions and assertions made by ICU regarding infringement of the '866 patent have caused and, if not enjoined, will continue to cause irreparable injury to RyMed.

### **SECOND COUNTERCLAIM**

#### **DECLARATORY JUDGMENT OF NON-INFRINGEMENT AND INVALIDITY OF THE '862 PATENT**

10. RyMed realleges and incorporates herein by reference the matters alleged in Paragraphs 1-9 of the Counterclaims.

11. As demonstrated by ICU's commencement of this action, an actual and justiciable controversy exists between RyMed and ICU as to the non-infringement and invalidity of the '862 patent.

12. RyMed has not infringed and is not infringing any valid and enforceable claim of the '862 patent, either directly, indirectly, literally, or under the doctrine of equivalents.

13. The claims of the '862 patent are invalid and unenforceable for failure to meet one or more of the requirements of patentability specified in Title 35 of the United States Code, including, without limitation, 35 U.S.C. §§ 102, 103 and/or 112.

14. RyMed has no adequate remedy at law. The actions and assertions made by ICU regarding infringement of the '862 patent have caused and, if not enjoined, will continue to cause irreparable injury to RyMed.

**THIRD COUNTERCLAIM**

**DECLARATORY JUDGMENT OF NON-INFRINGEMENT AND INVALIDITY  
OF THE '204 PATENT**

15. RyMed realleges and incorporates herein by reference the matters alleged in Paragraphs 1-14 of the Counterclaims.

16. As demonstrated by ICU's commencement of this action, an actual and justiciable controversy exists between RyMed and ICU as to the non-infringement and invalidity of the '204 patent.

17. RyMed has not infringed and is not infringing any valid and enforceable claim of the '204 patent, either directly, indirectly, literally, or under the doctrine of equivalents.

18. The claims of the '204 patent are invalid and unenforceable for failure to meet one or more of the requirements of patentability specified in Title 35 of the United States Code, including, without limitation, 35 U.S.C. §§ 102, 103 and/or 112.

19. RyMed has no adequate remedy at law. The actions and assertions made by ICU regarding infringement of the '204 patent have caused and, if not enjoined, will continue to cause irreparable injury to RyMed.

**FOURTH COUNTERCLAIM**

**DECLARATORY JUDGMENT OF NON-INFRINGEMENT AND INVALIDITY  
OF THE '592 PATENT**

20. RyMed realleges and incorporates herein by reference the matters alleged in Paragraphs 1-19 of the Counterclaims.

21. As demonstrated by ICU's commencement of this action, an actual and justiciable controversy exists between RyMed and ICU as to the non-infringement and invalidity of the '592 patent.

22. RyMed has not infringed and is not infringing any valid and enforceable claim of the '592 patent, either directly, indirectly, literally, or under the doctrine of equivalents.

23. The claims of the '592 patent are invalid and unenforceable for failure to meet one or more of the requirements of patentability specified in Title 35 of the United States Code, including, without limitation, 35 U.S.C. §§ 102, 103 and/or 112.

24. RyMed has no adequate remedy at law. The actions and assertions made by ICU regarding infringement of the '592 patent have caused and, if not enjoined, will continue to cause irreparable injury to RyMed.

**DEMAND FOR JURY TRIAL**

Pursuant to Federal Rule of Civil Procedure 38, RyMed hereby demands a trial by jury of this action.

**PRAYER FOR RELIEF**

WHEREFORE, RyMed prays for judgment and seeks relief against ICU as follows:

- a. A judgment dismissing, with prejudice, each and every one of ICU's claims in their entirety;
- b. A judgment declaring that RyMed has not and does not infringe any valid and enforceable claim of the '866 patent, either directly or indirectly, and either literally or under the doctrine of equivalents;
- c. A judgment declaring that RyMed has not and does not infringe any valid and enforceable claim of the '862 patent, either directly or indirectly, and either literally or under the doctrine of equivalents;

d. A judgment declaring that RyMed has not and does not infringe any valid and enforceable claim of the '204 patent, either directly or indirectly, and either literally or under the doctrine of equivalents;

e. A judgment declaring that RyMed has not and does not infringe any valid and enforceable claim of the '592 patent, either directly or indirectly, and either literally or under the doctrine of equivalents;

f. A judgment declaring that each and every claim of the '866 patent, the '862 patent, the '204 patent, and the '592 patent is invalid and/or unenforceable;

g. A judgment denying all remedies and relief sought by ICU in its Complaint;

h. A judgment declaring this case to be an exceptional case within the meaning of 35 U.S.C. § 285, and awarding RyMed its attorneys' fees, costs, and expenses incurred in this action as permitted by law; and

i. Such other and further relief as the Court may deem just and proper.

October 12, 2007

THE BAYARD FIRM

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**CERTIFICATE OF SERVICE**

The undersigned counsel certifies that, on October 12, 2007, he electronically filed the foregoing document with the Clerk of the Court using CM/ECF, which will send automatic notification of the filing to the following:

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The undersigned counsel further certifies that, on October 12, 2007, copies of the foregoing document were sent by email and hand to the above local counsel and by email and first class mail to the following non-registered participant:

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